IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al. v. AMERICAN HOME PRODUCTS CORPORATION	)	CIVIL ACTION NO. 99-20593 2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9040

Bartle, J. April 4, 2013

Christeen K. Rightnar ("Ms. Rightnar" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In February, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Daniel J. McGowan, M.D., F.A.C.C. Based on an echocardiogram dated July 30, 2002, Dr. McGowan attested in Part II of Ms. Rightnar's Green Form that claimant suffered from moderate mitral regurgitation and a reduced ejection fraction in the range of 50%

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2. (...continued)
Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

to 60%.[3] Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $512,025.[4]

In the report of claimant's echocardiogram, Dr. McGowan concluded claimant had "normal left ventricular systolic function with an estimated ejection fraction of 55 percent." An ejection fraction is considered reduced for purposes of a mitral valve claim it if is measured as less than or equal to 60%. See Settlement Agreement § IV.B.2.c.(2)(b)iv).

In January, 2006, the Trust forwarded the claim for review by Irmina Gradus-Pizlo, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Gradus-Pizlo determined that there was no reasonable medical basis for the attesting physician's finding that claimant had a reduced ejection fraction. Specifically, Dr. Gradus-Pizlo concluded that claimants's "[left ventricular systolic function] [is] estimated at 65%."

Based on Dr. Gradus-Pizlo's finding that claimant did not have a reduced ejection fraction, the Trust issued a

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3. Dr. McGowan also attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition is not at issue in this claim.

4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). A reduced ejection fraction is one of the complicating factors needed to qualify for a Level II claim. Although the Trust disputes claimant's level of mitral regurgitation, we need not resolve this issue given our determination with respect to claimant's ejection fraction.

post-audit determination denying Ms. Rightnar's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[5] In contest, claimant submitted affidavits from Roger W. Evans, M.D., F.A.C.P., F.A.C.C.,[6] Dan A. Francisco, M.D., F.A.C.C., and Gregory R. Boxberger, M.D., F.A.C.C., wherein they stated that there was a reasonable medical basis for Dr. McGowan's Green Form representation that claimant's echocardiogram, which was performed as part of the Trust's Screening Program,[7] demonstrated a reduced ejection fraction. Specifically, all three doctors concluded that claimant had an ejection fraction of 60%. Claimant argued therefore that she had established a reasonable medical basis for her claim because three Board-Certified Cardiologists agreed that she had a reduced ejection fraction. Ms. Rightnar also asserted that the auditing cardiologist "apparently did not understand the difference between his

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5. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Rightnar's claim.

6. Dr. Evans, Dr. Francisco, and Dr. Boxberger are no strangers to this litigation. According to the Trust, Dr. Evans has attested to at least 322 Green Forms on behalf of claimants seeking Matrix Benefits.

7. See Settlement Agreement § IV.A.1.a. (Screening Program established under the Settlement Agreement).

personal opinion ... and the 'reasonable medical basis' standard." (Emphasis in original.) Finally, claimant contended that she had satisfied her burden because the original auditing cardiologist who reviewed her echocardiogram found a reasonable medical basis for finding a reduced ejection fraction.[8]

The Trust then issued a final post-audit determination, again denying Ms. Rightnar's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Rightnar's claim should be paid. On July 6, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6410 (July 6, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response and a supplemental response upon the Special Master. The Trust submitted a reply on September 27, 2006 and claimant submitted a sur-reply on October 20, 2006. Under the Audit Rules, it is

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8. In PTO No. 5632 (Aug. 26, 2005), we authorized the Trust to re-audit the claims of certain Diet Drug Recipients, including Ms. Rightnar, who opted out of the Seventh Amendment to the Settlement Agreement but did not elect to submit the initial audit of their claims to the Claims Integrity Process, based on the Trust's allegations that these initial audits were not reliable.

within the Special Master's discretion to appoint a Technical Advisor[9] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether Ms. Rightnar has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she had a reduced ejection in the range of 50% to 60%. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

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9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

In support of her claim, Ms. Rightnar reasserts the arguments that she made in contest, namely, that the opinions of Dr. Evans, Dr. Francisco, and Dr. Boxberger provide a reasonable medical basis for Dr. McGowan's finding that she had a reduced ejection fraction. Claimant also contends that the concept of inter-reader variability accounts for the differences between the opinion of the attesting physician and that of the auditing cardiologist. According to claimant, there is an "absolute" inter-reader variability of 18% when evaluating an ejection fraction using Simpson's Rule, 16% when using the wall motion index, and 19% when using subjective visual assessment. Thus, Ms. Rightnar maintains that if the Trust's auditing cardiologist or a Technical Advisor concludes that an ejection fraction is as high as 79%, a finding of an ejection fraction of 60% by an attesting physician is medically reasonable.

The Trust counters that the supplemental opinions of Dr. Evans, Dr. Francisco, and Dr. Boxberger do not establish a reasonable medical basis for the claim because they do not rebut the specific findings of the auditing cardiologist. The Trust also contends that inter-reader variability does not account for the differences between the findings of the attesting physician and the auditing cardiologist because Dr. Gradus-Pizlo specifically determined that there is no reasonable medical basis for the finding of Dr. McGowan. Finally, the Trust notes that the finding of the original auditing cardiologist is irrelevant to the proper disposition of this claim because (1) Ms. Rightnar

chose to have her claim re-audited pursuant to PTO No. 5632 and (2) the basis for PTO No. 5632 was our determination that updated training for the Trust's auditing cardiologist's was warranted to protect the integrity of the Settlement Agreement.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Rightnar had a reduced ejection fraction. Specifically, Dr. Vigilante observed that:

> The left ventricle was completely normal in size with excellent contractility and no regional motion wall abnormalities. Mild concentric left ventricular hypertrophy was noted. The left ventricular ejection fraction appeared to be approximately 65% when evaluated in the parasternal long axis, parasternal short axis, apical four chamber and apical two chamber views. I digitized the cardiac cycles in which there was excellent endocardial definition of the left ventricle in end systole and end diastole and calculated the ejection fraction using Simpson's method. The ejection fraction was calculated at 69%. The [ejection fraction] never came close to approaching 60%.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. As an initial matter, claimant does not adequately refute the findings of the auditing cardiologist or the Technical Advisor. Dr. Gradus-Pizlo reviewed claimant's echocardiogram and specifically determined that there was no reasonable medical basis for Dr. McGowan's representation that claimant had a reduced ejection fraction because

Ms. Rightnar's ejection fraction was estimated to be 65%.[10] In addition, Dr. Vigilante concluded that claimant's "left ventricle was completely normal in size with excellent contractility and no regional motion wall abnormalities" and that her "ejection fraction was calculated at 69%."[11] Neither claimant nor her experts identified any particular errors in the conclusions of the auditing cardiologist or the Technical Advisor. Mere disagreement with the auditing cardiologist or the Technical Advisor without identifying any specific errors by them is insufficient to meet a claimant's burden of proof.[12]

In addition, claimant's reliance on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation that she had a reduced ejection fraction in the range of 50 to 60% is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's finding cannot be medically reasonable where the

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10. Thus, we reject claimant's argument that the auditing cardiologist substituted her personal opinion for that of the attesting physician.

11. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

12. For this reason, the reasons set forth in PTO No. 5632, and because claimant elected to have her claim re-audited, we also reject claimant's argument that the finding of the original auditing cardiologist provides a reasonable medical basis for the attesting physician's representations that she had a reduced ejection fraction.

auditing cardiologist estimated that claimant's echocardiogram demonstrated an ejection fraction of 65% and the Technical Advisor concluded "[t]he ejection fraction was calculated at 69%" and "never came close to approaching 60%." Adopting claimant's argument that inter-reader variability would expand the range of an ejection fraction by as much as ±19% would allow a claimant to recover benefits with an ejection fraction as high as 79%. This result would render meaningless this critical provision of the Settlement Agreement.[13]

Finally, to the extent claimant argues that there is a reasonable medical basis for Dr. McGowan's representation of a reduced ejection fraction because claimant's echocardiogram was performed as part of the Trust's Screening Program, such argument is misplaced. The Settlement Agreement clearly provides that the sole benefit that an eligible class member is entitled to receive based on an echocardiogram performed in the Screening Program is a limited amount of medical services or a limited cash payment:

> All Diet Drug Recipients in Subclass 2(b) and those Diet Drug Recipients in Subclass 1(b) who have been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of

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13. Moreover, the Technical Advisor took into account the concept of inter-reader variability as reflected in his statement, "there is no reasonable medical basis for the Attesting Physician's answer to Green Form Question F.8. That is, the echocardiogram of July 30, 2002 demonstrated an ejection fraction of 69%. An echocardiographer could not reasonably conclude that an ejection fraction of 50-60% was present on this study even taking into account inter-reader variability."

> the Screening Period, will be entitled to receive, at the Class Member's election, either (i) valve-related medical services up to $10,000 in value to be provided by the Trust; or (ii) $6,000 in cash.

Id. § IV.A.1.c. Thus, by the plain terms of the Settlement Agreement, a Screening Program echocardiogram does not automatically entitle a claimant to Matrix Benefits.

Indeed, this conclusion is confirmed by the Settlement Agreement provisions concerning claimants eligible for Matrix Benefits. Specifically, claimants receiving a diagnosis of FDA Positive or mild mitral regurgitation merely become eligible to seek Matrix Benefits. See id. § IV.B.1. Further, adopting claimant's position would be inconsistent with Section VI.E. of the Settlement Agreement, which governs the audit of claims for Matrix Benefits, as well as this court's decision in PTO No. 2662 (Nov. 26, 2002), which mandated a 100% audit for all claims for Matrix Benefits. As nothing in the Settlement Agreement supports the conclusion that a favorable Screening Program echocardiogram for purposes of Fund A Benefits results in an immediate entitlement to Matrix Benefits, we decline claimant's request to interpret the Settlement Agreement in this fashion.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had a reduced ejection fraction. Therefore, we will affirm the Trust's denial of Ms. Rightnar's claim for Matrix Benefits.